

Appl. No. 10/807,449
Response dated September 4, 2009
In response to Office Action dated March 4, 2009

REMARKS

Claims 1 and 3-43 are pending. Of those claims, claims 3, 5, 9, 12-18, 21-22 and 25-43 are withdrawn.

Revocation of Power of Attorney with New Power of Attorney and Change of Correspondence Address

Applicants filed a *Revocation of Power of Attorney with New Power of Attorney and Change of Correspondence Address* on August 16, 2007. Since that time, applicants have not received any further communication from the United States Patent and Trademark Office concerning the *Revocation* in connection with this application. In fact, the USPTO PAIR website still reflects the former attorney names and correspondence address and does not indicate the new attorneys and correspondence address of record. Applicants respectfully request that the United States Patent and Trademark Office communicate the status of the *Revocation* to the undersigned in the next communication.

THE REJECTIONS

35 U.S.C. § 112, second paragraph (indefiniteness)
Claims 1, 6-8, 11, 19-20, 23 and 24

Claims 1, 6-8, 11, 19-20 and 23-24 are rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. Specifically, the Examiner states that the recitation of "bystander cells" is indefinite because the term appears to be used as the

therapeutic substance in the instant claims which is inconsistent with the common usage of the term in the art. Applicants respectfully traverse.

Contrary to the Examiner's contention, the specification provides that bystander cells of the present invention are universal cells that may express a cytokine and/or a cancer therapeutic agent (*see, e.g.*, page 29, lines 19-20; page 37, line 1 to page 39, line 10). The specification further provides that bystander cells may be combined with the autologous and allogeneic approach (*see, e.g.*, page 37, lines 20-23). The specification also provides that the use of bystander cells provides a therapeutic advantage in that administration of a cytokine-expressing bystander cell line and at least one additional cancer therapeutic agent (expressed by the same or a different cell line) to a patient with cancer, together with an autologous cancer antigen results in an effective immune response to a tumor (*see, e.g.*, page 39, lines 4-10). Thus, the specification provides a clear definition for the term "bystander cells" and applicants request that the Examiner withdraw the rejection.

35 U.S.C. §§ 102(a) and (e)
Claims 1, 4, 6-8, 10, 11, 19, 20, 23 and 24

Claims 1, 4, 6-8, 10, 11, 19-20, 23 and 24 are rejected under 35 U.S.C. §§ 102(a) and 102(e) over US Patent Publication 2003/0035790 ("Chen"). Specifically, the Examiner states that the use of the term "bystander cells" appears to be inconsistent with its conventional usage in the art. The Examiner also states that the term "allogeneic cells" refers to cells which are genetically distinct from those of the patient and that *Chen* discloses that cells used in their therapeutic methods may be obtained from umbilical cord blood or fetal liver, which suggests that these cells are allogeneic. Applicants respectfully traverse.

First, as discussed above, applicants submit that the term "bystander cells" is clearly defined in the specification and one of skill in the art would understand the meaning of the term as used in the present invention.

Second, applicants submit that *Chen*'s disclosure that cells obtained from umbilical cord blood or fetal liver may be used in their therapeutic methods still fails to teach each and every limitation of the instant claims. The instant claims recite administering a cytokine-expressing cellular vaccine comprising proliferation-incompetent *tumor cells* that express GM-CSF, wherein the tumor cells are selected from the group consisting of allogeneic and bystander cells. *Chen*'s cells obtained from umbilical cord blood or fetal liver are *not* proliferation-incompetent *tumor cells* that express GM-CSF. Instead, *Chen* merely discloses injecting MCA26 tumor-bearing mice intratumorally with an adenovirus expressing mGM-CSF (see, e.g., Example 10) or implanting MCA26 tumor cells into the left lobe of the liver and then subsequently injecting adenovirus expressing mGM-CSF into tumor-bearing mice (see, e.g., Example 11). *Chen* does not teach or suggest proliferation-incompetent tumor cells that express GM-CSF, wherein the tumor cells are selected from the group consisting of allogeneic and bystander cells. Thus, applicants submit that Chen fails to teach each and every limitation of the claims.

In view of the above remarks, applicants respectfully request that the Examiner withdraw this rejection.

Appl. No. 10/807,449
Response dated September 4, 2009
In response to Office Action dated March 4, 2009

35 USC §101 - Nonstatutory Double Patenting
Claims 1, 4, 6-8, 10, 11, 19-20, 23 and 24

Claims 1, 4, 6-8, 10, 11, 19-20, 23 and 24 are provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-33 of copending U.S. Application No. 10/404,662.

Applicants request that this provisional rejection be held in abeyance until this application or copending application 10/404,662 is allowed. At that time, applicants will file a Terminal Disclaimer as is appropriate and proper.

CONCLUSION

In view of the foregoing remarks, applicants request that the Examiner favorably reconsider this application and allow the claims pending herein. If the Examiner believes that a telephone conference would expedite allowance of this application, she is invited to telephone the undersigned at any time.

Respectfully submitted,

/CONNIE WONG/

James F. Haley, Jr. (Reg. No. 27,794)
Connie Wong (Reg. No. 62,901)
Attorneys for Applicants
c/o ROPES & GRAY LLP
(Customer No. 1473)
1211 Avenue of the Americas
New York, New York 10036
Telephone (212) 596-9000